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Susan Mosier, MD, Acting Secretary

Department of Health & Environment

Sam Brownback, Governor

Drug Utilization Review Board
Meeting Agenda, Open Session
April 8, 2015 10am – 2pm

Meeting Location
HP Enterprise Services, Capital Room
6700 SW Topeka Blvd, Bldg. 283 J, Topeka, KS 66619

Board Members

James Backes, PharmD
Tim Heston, DO
John Kollhoff, PharmD
Judy McDaniel Dowd, PA-C
Russell Scheffer, MD
Kevin Waite, PharmD
Roger Unruh, DO

KDHE-DHCF Staff

Liane Larson, PharmD
Kelley Melton, PharmD

HP Enterprise Services/HID Staff

Ariane Casey, PharmD
Karen Kluczykowski, RPh
Nancy Perry, RN

MCO Staff

Jonalan Smith, PharmD, FASCP, **Sunflower State Health Plan**
Jennifer Murff, RPh, **UnitedHealthcare Community Plan**
Lisa Todd, RPh, **Amerigroup**

I. CALL TO ORDER

A. Announcements

II. OLD BUSINESS

A. Review and Approval of January 14, 2015 Meeting Minutes

B. Tabled Prior Authorization Criteria

1. **Onfi® (clobazam)**
   Onfi is an anti-epileptic drug indicated for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age and older. In April 2012, the DUR board approved diagnosis restrictions, but since that time, utilization has increased. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information. The DUR board tabled this topic at the January 2015 DUR meeting after a discussion regarding efficacy in off-labeled indications. The prior authorization criteria has remained the same. Clinical information regarding appropriate use is presented.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

III. NEW BUSINESS

A. Revised Prior Authorization (PA) Criteria

1. **Sovaldi® (sofosbuvir)**
   Prior authorization criteria for Sovaldi was last revised in July 2014, and at that time, the guidelines have been updated to define those patients who should be treated first. The criteria is being revised to exclude specific staging of fibrosis and to include clarification of which patients are candidates for treatment with Sovaldi® (e.g., advanced liver disease, extrahepatic manifestions, and complications due to chronic hepatitis C).
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **Olysio® (simeprevir)**
   Prior authorization criteria for Olysio was last revised in July 2014, and at that time, the guidelines have been updated to define those patients who should be treated first. The criteria is being revised to exclude specific staging of fibrosis and to include clarification of which patients are candidates for treatment with Olysio® (e.g., advanced liver disease, extrahepatic manifestions, and complications due to chronic hepatitis C).
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

3. **Weight Loss Drugs (Saxenda® [liraglutide])**
   The prior authorization criteria for weight loss agents was last revised in January 2015, and since that time, a new agent has been approved. The prior authorization criteria is being revised to include the new agent, Saxenda.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

4. **Kalydeco® (ivacaftor)**
   Prior authorization criteria for Kalydeco was last revised in July 2014, and since that time, a new gene mutation and pediatric age group has been approved. Kalydeco is now approved for use in patients with a gene mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene R117H and for patients as young as 2 years of age. The prior authorization criteria is being revised to include this new gene mutation and to include ages 2-5 years.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

5. **Supprelin LA® (histrelin)**
   Prior authorization criteria for Supprelin LA was approved in October 2011. It is approved for the treatment of central precocious puberty (CPP) in children. Revised prior authorization criteria are being proposed to include other commonly used hormone evaluations for the diagnosis of CPP.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

B. New PA Criteria

1. **Granix® (tbo-filgrastim)**
   VGranix is a recently approved colony stimulating agent. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **Glyxambi® (empagliflozin/linagliptan)**
   Glyxambi is a recently approved sodium-glucose co-transporter 2 (SGLT2) inhibitor combination indicated for the treatment of patients with type 2 diabetes mellitus (T2DM). Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

3. **Cosentyx® (secukinumab)**
   Cosentyx is an immunomodulator indicated for the treatment of moderate to severe plaque psoriasis. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents in this class.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

4. **Lupaneta Pack® (leuprolide depot; norethindrone tablets)**
   Lupaneta Pack is a gonadotropin-releasing hormone analog/progestin combination medication indicated for the management of painful symptoms of endometriosis. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved indication.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

5. **Blincyto® (blinatumomab)**
   Blincyto is an antineoplastic monoclonal antibody indicated for the treatment of acute lymphoblastic leukemia (ALL). Prior authorization criteria is being proposed to ensure appropriate use based on FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

6. **Demser® (metyrosine)**
   Demser is an agent used for the treatment of pheochromocytoma in patients 12 years of age and older. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

7. **Ragwitek® (short ragweed pollen allergen extract)**
   Ragwitek is an agent indicated as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis in patients aged 18 through 65 years of age. Diagnosis is confirmed by a positive skin test or *in vitro* testing for pollen-specific IgE antibodies for short ragweed pollen. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

8. **Grastek® (Timothy grass pollen allergen extract)**
   Grastek is an agent indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis in patients aged 5 through 65 years of age. Diagnosis is confirmed by a positive skin test or *in vitro* testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

9. **Oralair® (Sweet vernal, Orchard, Perennial rye, Timothy, and Kentucky blue grass mixed pollens allergens extract)**
   Oralair is an agent indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis in patients aged 10 through 65 years of age. Diagnosis is confirmed by a positive skin test or *in vitro* testing for pollen-specific IgE antibodies for any of the five grass species contained in the product. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

C. MISCELLANEOUS ITEMS

1. **Managed Care Organization Annual Reports**
   Amerigroup, United Healthcare, and Sunflower will present reports detailing utilization trends and provider education efforts for 2014.
   i. Overall MCO Utilization Data – Kelley Melton, PharmD
   ii. Amerigroup Individual Report – Lisa Todd, RPh
   iii. United Healthcare Individual Report – Jennifer Murff, RPh
   iv. Sunflower Individual Report – Jonalan Smith, PharmD
   v. *Public Comment
   vi. Board Discussion

IV. OPEN PUBLIC COMMENT

V. ADJOURN

Lunch will be provided for the DUR Board members.
The next DUR Board meeting is scheduled for July 8, 2015.

*Public comment is limited to five minutes per product; additional time will be allowed at the DUR Board's discretion. Informal comments will be accepted from members of the audience at various points in the agenda.

****THIS AGENDA IS SUBJECT TO CHANGE****